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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/552,272	04/19/2000	Li Fang	913.6600CIP	3198

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EXAMINER

EPPS FORD, JANET L

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 02/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

09/552,272

Applicant(s)

FANG ET AL.

Examiner

Janet L. Epps-Ford, Ph.D.

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 21 January 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The reply was filed after the date of filing a Notice of Appeal, but prior to the date of filing an appeal brief. The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 1, 5, 6, 10 and 14-57 would remain rejected for the reasons of record.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____.
13. ☒ Other: See Continuation Sheet.

Janet L. Epps-Ford, Ph.D.
Patent Examiner
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Continuation of 3. NOTE: Applicants have amended instant claims 16, 19, 28, and 38-40 to recite a first nucleic acid fragment "comprising SEQ ID NO: 48, SEQ ID NO: 49, SEQ ID NO: 50 or a fragment that will hybridize under low or high stringency conditions to a reference nucleic acid molecule that is precisely complementary to SEQ ID NO: 48, SEQ ID NO: 49, or SEQ ID NO: 50, in which the nucleic acid fragment is derived from nucleic acid molecule comprising a cold shock inducible gene. Applicant's amendment would therefore require a further consideration of the prior art and a new search, since the examiner had not previously considered and/or searched fragments which hybridize under low or high stringency conditions to SEQ ID NO: 48, 49, or 50, and further wherein said fragment is derived from a first nucleic acid molecule comprising a first cold shock inducible gene having a protein coding region. Moreover, Applicant's amendment would raise new issues under 35 USC 112, 1st paragraph since Applicants do not provide an adequate written description of the full scope of nucleic acid molecules encompassed by the first nucleic acid fragments according to the invention as proposed by the suggested claim amendments. Additionally, since Applicants have added new claims 58-65, and have introduced a new sequence structure into claim 55 (specifically nucleotides 1-25 of SEQ ID NO: 55), a new search and new considerations are required to examine the instantly amended claims

Continuation of 11. does NOT place the application in condition for allowance because: See attached reply to Applicant's arguments traversing the rejection of claims 1, 5-15 and 57 under 35 USC § 102.

Continuation of 13. Other: Upon review of Applicant's arguments traversing the rejection of claims 16-57, Applicant's amendment to claims 16, 19, 28, and 38-40 does not overcome the pending rejection of the instant claims under 35 USC 112, 1st paragraph for lack of sufficient written description. In regards to the new amendment to the claims to recite a first or second nucleic acid fragment comprising a fragment that will hybridize under low or high stringency conditions to a reference nucleic acid molecule that is precisely complementary to SEQ ID NO: 48, 49, 50, or nucleotide 56-117, raises new issues under 35 USC 112, 1st paragraph. In particular, the genus of first nucleic acid fragments encompassed by the proposed claim amendments read on nucleic acid molecules comprising less than 13 nucleotides, including nucleic acid molecules including only one nucleotide from SEQ ID NO: 48-50, and hybridizing under low stringency conditions to a reference nucleic acid that is precisely complementary to SEQ ID NO: 48, 49, or 50. Since the instant claims are drawn to a nucleic acid sequence, more than just functional language, and a method of isolating the nucleic acid fragments is required since there is no obvious correlation between the recited function (namely that is functions to enhance translation) and the corresponding nucleic acid structure associated with said function. See MPEP § 2163, which states "[A] biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." Possession cannot be demonstrated by a means for isolating an invention.

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1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Amendment

Claim Rejections - 35 USC § 102

2. Claims 1, 5-15 and 57 remain rejected as being anticipated by Goldstein et al. for the reasons of record set forth in the Official Action mailed 9-13-01; Claims 1, 5-6 and 57 remain rejected as being anticipated by Oppenheim et al. (US Patent No. 5,726,039) or Oppenheim et al. (US Patent No. 5,654,169), for the reasons of record set forth in the Official Action mailed 4-07-04.

Applicant's arguments filed 1-21-05 have been fully considered but they are not persuasive. Applicants traverse the instant claims on the grounds that the basic nature of the isolated nucleic acid molecules having a sequence of nucleotides 123-132 of SEQ ID NO: 55, SEQ ID NO: 49, or SEQ ID NO: 50 recited in claim 1 is that each is a 13 nucleotide-long sequence that base pairs with positions 10-35-1023 of 16S rRNA, and that nucleotides 1-11 of SEQ ID NO: 55, and nucleotides 56-117 of SEQ ID NO: 55 have similar specific functions. According to Applicants, none of the sequences recited in claim 1 include a Shine-Delgarno sequence, and initiation codon, a protein coding region or a promoter. Thus, in the isolated form in which they are claimed, the sequences are not a part of a functional gene or vector and cannot be transcribed. This is basic nature of the isolated nucleic acid molecules of claim 1. Contrary to Applicant's assertions, claim 1 merely recite isolated nucleic acid molecules which consists essentially of certain sequence structures. However, there is no specific reference to any particular characteristic that is required by these isolated nucleic acid molecules recited in the instant

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claims, although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). According to MPEP § 2111.01 [R-2] “[d]uring examination the USPTO must give claims their broadest reasonable interpretation.)< This means that the words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification.” If Applicants intended that the nucleic acid molecules recited in claim 1 be limited to those having a particular characteristic, Applicants should add that particular characteristic as a limitation in the instant claims, since Applicants are relying on a characteristic that is not immediately obvious to ordinary practitioner, to distinguish the claimed invention from the prior art. Moreover, Applicants argue that none of the sequences recited in claim 1 include a Shine-Delgarno sequence and initiation codon, a protein coding region or a promoter. However, contrary to Applicant’s assertions, Applicant’s specification (pages 28-29) clearly states, “the expression plasmids (*i.e. vectors*) of the invention may comprise additional sequences known in the art to facilitate the efficient translation of the expressed gene. Such sequences may include a Shine-Dalgarno sequence, situated between the S'UTR sequence and the restriction sites) and/or a DNA fragment encoding a downstream box, situated between the Shine-Dalgarno sequence and the restriction sites). The source of the Shine-Dalgarno sequence is not especially limited, and may be derived from cold shock proteins or may be from another gene. Such expression plasmids are capable of directing high level expression of a heterologous gene for a prolonged period of time under conditions of physiological stress that elicit a cold shock response of a bacterium.” Therefore, Applicant’s own specification teach that the presence of a Shine-Delgarno sequence, or other sequences that facilitate the efficient translation

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of an expressed gene may be comprised within the nucleic acid molecules of the present invention, and do not materially affect the basic characteristics of the claimed invention. Although the sequences recited in the cited references contain additional elements, the sequence recited in Goldstein and Oppenheim et al. read on the claimed invention since the instant isolated nucleic acid molecules "consist essentially" of nucleotides 1-11 of SEQ ID NO: 55, nucleotides 56-117 of SEQ ID NO: 55, nucleotides 123-135 of SEQ ID NO: 55, SEQ ID NO: 49 or SEQ ID NO: 50, and Applicants have not defined what specified elements would materially affect the basic and novel characteristic(s) of the claimed invention in either the claims or the specification as filed. Absent evidence to the contrary, the nucleic acid structures disclosed in both Goldstein et al. and Oppenheim et al., corresponding to the 5'UTR of the *cspA* cold shock inducible gene of *E. coli*, the *cspA* gene functions as a cold shock inducible gene as recited in the instant claims, and furthermore the 5'UTR of the *cspA* gene comprises (i.e. consists essentially of) the entire sequence of SEQ ID NO: 55 of the instant application. Applicant's arguments do not take the place of evidence that the nucleic acid molecules disclosed by Goldstein et al. and Oppenheim et al. do not read on the isolated nucleic acid molecules of the instant claims.



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